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07/330,446	03/30/89	YOSHIMURA	1173145P

COOK, D

EXAMINER

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1814

ART UNIT

PAPER NUMBER

02/10/92
DATE MAILED:

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 11/15/91 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892. 2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, Form PTO-152
5. Information on How to Effect Drawing Changes, PTO-1474. 6.

Part II SUMMARY OF ACTION

1. Claims 1-7, 9-25 are pending in the application.

Of the above, claims 1-7, 20-25 are withdrawn from consideration.

2. Claims 8 have been cancelled.

3. Claims _____ are allowed.

4. Claims 9-19 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

Claims 1-7 and 9-25 are pending in the instant application. Claim 8 was canceled in paper no. 8.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-19 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the sequence of a human monocyte chemoattractant peptide, as disclosed by applicants, for reasons of record. See MPEP 706.03(n) and 706.03(z).

This rejection is maintained from the previous Office Action. Claims 9-11 are drawn to a "bioequivalent" peptide which possesses a high degree of homology. There are many peptides which could fit into this group and it would require undue experimentation to determine all of those proteins. The specification discloses only one peptide and the instant claims are thus beyond the breadth of the enabled invention.

Claims 9-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 are drawn to a biological equivalent of a monocyte chemoattractant protein which possesses a high degree of homology. It is uncertain what is intended by "high degree of homology", i.e. what level of homology is intended?

Claims 9-19 are rejected under 35 U.S.C. 103 as being unpatentable over Ramb et al., Valente et al., or Yoshimura et al., for reasons of record.

All of the references disclose proteins that are approximately the same molecular weight and which possess chemotactic activity for human

monocytic cells, and thus appear to disclose the same protein as the one described by the present application. It would have been obvious to one of ordinary skill in the art to determine the amino acid sequence of this protein, to obtain its DNA sequence, and to further clone this gene. The motivation would have been to obtain large quantities of the protein for further study and possible therapeutic application.

Applicants assert that the Yoshimura et al. reference is not applicable as prior art because it was published within one year of applicants' filing date. This argument has been fully considered but is not deemed persuasive. Yoshimura et al. is applicable to the instant application under the 35 USC 102(a) criteria ("known or used by others...or described in a printed publication...before the invention thereof"). Applicants also state that a Declaration in accordance with In re Katz will be filed. As of the writing of this Office Action, no such declaration has been received. The reference is thus deemed to be applicable under 35 USC 103 and the rejection stands.

Applicants further assert that neither Ramb et al. nor Valente et al. describe isolation of the protein. This argument has been fully considered but is not deemed to be persuasive in light of the fact that each reference teaches, in detail, purification procedures involving chromatography and electrophoresis. The references also describe characterization of the protein, which could not have been accomplished without having first purified it.

Applicants also argue that it would not have been obvious to clone the gene encoding said protein. This argument is also not deemed to be persuasive because cloning of a purified protein was well-known in the art at the time the invention was made. One of ordinary skill in the art would have been able to obtain the DNA sequence using oligonucleotide probes derived from the amino acid sequence and then to clone the gene. Such methodology is well-known and has become commonplace in the art.

In addition, applicants have not adequately differentiated their protein from that described by Ramb et al. and Valente et al. Applicants

argue that the protein is not the same as that described by Valente et al. by pointing out that the molecular weights of the two proteins are different. This is not deemed to be persuasive in view of the statements found in the Yoshimura et al. reference. Yoshimura et al. state, "If we assume that the peptide [Valente et al. peptide], like LDCF, has a molecular mass of approximately half the value estimated from SDS-PAGE, the amino acid composition is similar to that of LDCF" (page 1960). In addition, the proteins described by Ramb et al., Valente et al., Yoshimura et al., and the present application have the same molecular weight (approximately 15,000 kD, as measured by SDS-PAGE) and all possess monocyte chemoattractant activity. Therefore, because applicants have not definitively differentiated their protein from those described by the prior art, the protein of the present application is deemed to be obvious in view of the prior art.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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This application contains claims 1-7 and 20-25 drawn to an invention non-elected with traverse in Paper No. 8. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP §21.01.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1814.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Dian Cook whose telephone number is (703) 308-0452. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
ART UNIT 187
1814